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10/649,127	08/27/2003	Edward N. Barthell	4003-008	4764

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EXAMINER	
RANGREJ, SHEETAL	
ART UNIT	**PAPER NUMBER**
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,127	BARTHELL, EDWARD N.	
	Examiner	Art Unit	
	Sheetal R. Rangrej	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

37 CFR 1.131 Affidavit

Applicant has submitted an affidavit to remove Epler et al. (2003/0187615) as a reference applied under 35 U.S.C. § 103(a) in the previous Office Action. The affidavit filed on 15 March 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Epler reference for the following reasons:

Where conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to allege that applicant or patent owner had been diligent. Ex parte Hunter, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence.

In determining the sufficiency of a 37 CFR 1.131 affidavit or declaration, diligence need not be considered unless conception of the invention prior to the effective date is clearly established, since diligence comes into question only after prior conception is established. Ex parte Kantor, 177 USPQ 455 (Bd. App. 1958).

What is meant by diligence is brought out in Christie v. Seybold, 1893 C.D. 515, 64 O.G. 1650 (6th Cir. 1893). In patent law, an inventor is either diligent at a given time or he is not diligent; there are no degrees of diligence. An applicant may be diligent within the meaning of the patent law when he or she is doing nothing, if his or her lack of activity is excused. Note, however, that the record must set forth an explanation or excuse for the inactivity; the USPTO or courts will not speculate on possible explanations for delay or inactivity. See In re Nelson, 420 F.2d 1079, 164 USPQ 458 (CCPA 1970). Diligence must be judged on the basis of the particular

facts in each case. See MPEP § 2138.06 for a detailed discussion of the diligence requirement for proving prior invention.

Under 37 CFR 1.131, the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive (i.e., filing a United States patent application). Note, therefore, that only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" is not relevant to an affidavit or declaration under 37 CFR 1.131. See Ex parte Merz, 75 USPQ 296 (Bd. App. 1947).

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Epler reference to either a constructive reduction to practice or an actual reduction to practice.

An applicant must account for the entire period during which diligence is required. *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); *Fitzgerald v. Arbib*, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be

embodied in some structure other than a mere drawing.); *Kendall v. Searles*, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) (Diligence requires that applicants must be specific as to dates and facts.). MPEP 2138.05.

Applicant claims that he conceived of the invention in fall 2001 and constructively reduced the invention to practice by filing on 10/11/2002. Therefore, Applicant must show diligence from prior to 3/26/2002 up to the filing date of the application. Applicant has failed to provide sufficient evidence of diligence during this time period. For example, Applicant has failed to account for the time period between 4/19/2002-05/13/2002 and 05/13/2002-10/11/2002. Thus, the affidavit is deemed insufficient to overcome the Epler reference. The applicant also doesn't account for every day that he was diligent.

According to MPEP § 715.07, Applicant should specifically refer to each exhibit relied upon in the affidavit or declaration, in terms of what it is relied upon to show. The affidavit or declaration and exhibits must clearly explain which facts or data Applicant is relying on to show completion of his or her invention prior to the particular date. Vague and general statements in broad terms about what the exhibits describe along with a general assertion that the exhibits describe a reduction to practice "amounts essentially to mere pleading, unsupported by proof or a showing of facts" and, thus, does not satisfy the requirements of 37 CFR 1.131(b). *In re Borkowski*, 505 F.2d 713, 184 USPQ 29 (CCPA 1974). Applicant must give a clear explanation of the exhibits pointing out exactly what facts are established and relied on by Applicant. 505 F.2d at 718-19, 184 USPQ at 33. See also *In re Harry*, 333 F.2d 920, 142 USPQ 164 (CCPA 1964) (Affidavit "asserts that facts exist but does not tell what they are or when they occurred."). A general allegation that the invention was completed prior to the date of the reference is not

sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131.

Prosecution History Summary

1. Claims 1-23 are pending.

2. Claims 24-26 are withdrawn.

Priority

3. Application 10/649127 holds the benefit of the provisional application, 60/418104.

Restriction

4. Applicant's election with traverse of claims 1-23 is acknowledged. The traversal is on the ground(s) that undue searching should not be required. This is not found persuasive because Examiner believes that the restriction is proper since the subcombinations are distinct from each other and are shown to be separately usable. Invention I (claims 1-23) has a separate utility such as a method for detecting a bio-emergency. Invention I is classified in class 705, subclass 2. Invention II has a separate utility such as a method for compiling medical information. Invention II is classified in class 705, subclass 3. Examiner notes that it would be a serious burden to search all inventions given their separate status in the art as noted above.

5. The requirement is still deemed proper and is therefore made FINAL. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the free required under 37 CFR 1.17(i).

Specification

8. The examiner has reviewed applicant's arguments and has withdrawn the objections made to the specification.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Reference A.

11. As per claim 1, Reference A teaches the method of detecting a bio-emergency:

a. Receiving patient health information at a plurality of health care facilities (page 3, paragraph 0030, lines 4-7).

b. Transmitting, simultaneously with said receiving step, the patient health information to a bio-surveillance network (page 4, paragraph 0038, lines 1-3).

c. Compiling the patient health information to create compiled health data (page 3, paragraph 0030, lines 9-12; page 4 paragraph 0035, lines 1-15).

12. As per claim 2, the method of claim 1 is as described above. Reference A further teaches wherein the bio-surveillance network includes at least one regional repository that communicates directly with at least one of the health care facilities (page 2, paragraph 0019, lines 10-13). In

light of the specification, the examiner interprets health officials to be the same as health care facilities.

13. As per claim 3, the method of claim 2 is as described above. Reference A further teaches wherein the regional repository is a regional health department (page 4, paragraph 0038, lines 1-3). In light of the specification, the examiner interprets the central database to be the same as a regional health department.

14. As per claim 4, the method of claim 2 is as described above. Reference A further teaches wherein the at least one regional repository includes a plurality of regional repositories (page 6, paragraph 0054, lines 1-3).

15. As per claim 5, the method of claim 4 is as described above. Reference A further teaches wherein said compiling step is performed at the regional repositories (page 4, paragraph 0038, lines 1-8). In light of the specification, the examiner interprets the central collecting computer to be the same as a regional repository.

16. As per claim 6, the method of claim 5 is as described above. Reference A further teaches communicating the compiled health data to at least one group including the regional repositories (page 6, paragraph 0041, lines 11-14 and lines 19-23) and a centralized recipient (page 3, paragraph 0030, lines 17-19).

17. As per claim 7, the method of claim 5 is as described above. Reference A further teaches the bio-surveillance network includes a centralized recipient that receives the compiled health care data from at least one of the regional repositories (page 3, paragraph 0030, lines 17-19).

18. As per claim 8, the method of claim 7 is as described above. Reference A further teaches comparing the compiled health data to a threshold (page 5, paragraph 0051, lines 8-12).

19. As per claim 9, the method of claim 8 is as described above. Reference A further teaches generating a warning signal in response to said comparing step (page 5, paragraph 0047, lines 5-10).

20. As per claim 10, the method of claim 9 is as described above. Reference A further teaches communicating the warning signal to at least one of a group including the health care facilities (page 5, paragraph 0048, lines 2-7), a law enforcement agency (page 3, paragraph 0030, line 19).

21. As per claim 11, the method of claim 10 is as described above. Reference A further teaches communicating the warning signal is performed automatically in response to said comparing step (page 5, paragraph 0048, lines 2-7).

22. As per claim 12, the method of claim 7 is as described above. Reference A further teaches the centralized recipient is the Centers for Disease Control (page 3, paragraph 0030, line 19).

23. As per claim 13, the method of claim 1 is as described above. Reference A further teaches wherein the patient health information includes triage information (page 3, paragraph 31, lines 1-3).

24. As per claim 14, the method of claim 13 is as described above. Reference A further teaches wherein the triage information includes symptom information (page 3, paragraph 31, lines 1-6).

25. As per claim 15, the method of claim 14 is as described above. Reference A further teaches the triage information includes a primary complaint (page 3, paragraph 31, lines 1-6).

26. As per claim 16, the method of claim 15 is as described above. Reference A further teaches the triage information includes a secondary complaint (page 3, paragraph 31, lines 1-9). In light of the specification, the examiner interprets patient presenting symptoms is the same as a secondary complaint.

27. As per claim 17, the method of claim 14 is as described above. Reference A further teaches categorizing the symptom information (page 5, paragraph 0053, lines 8-18; page 6, paragraph 0054, lines 1-11). In light of the specification, the examiner interprets symptoms to be categorized if used to predict certain illnesses and injuries.

28. As per claim 18, the method of claim 1 is as described above. Reference A further teaches categorizing step includes generating syndromic data (page 5, paragraph 0051, lines 3-6).

29. As per claim 19, the method of claim 1 is as described above. Reference A further teaches said receiving step is performed using proprietary software (page 3, paragraph 0030, lines 4-9). In light of the specification, the examiner interprets the patient information is being captured by the software.

30. As per claim 20, the method of claim 1 is as described above. Reference A further teaches wherein said transmitting step is implemented via the Internet (page 4, paragraph 0041, lines 16-19).

31. As per claim 21, Reference A teaches a method of detecting a bio-emergency:

a. Receiving individual triage patient health information at a plurality of health care facilities from each of a plurality of patients (page 3, paragraph 0031, lines 1-5).

b. On a patient-by-patient basis, electronically recording triage data for that patient in a computer of the associated health care facility, the triage data for each patient

containing at least some of the received health information for that patient (page 3, paragraph 0030, lines 4-7 and paragraph 0031, lines 1-8).

c. Upon recording the triage data for each patient, transmitting at least a portion of the recorded triage data to a computer for one of a plurality of regional repositories automatically and in at least near real-time, the computer for each of the regional repositories receiving triage data from a computer for each of a plurality of the health care facilities (page 5, paragraph 0047, lines 5-10 and paragraph 0048, lines 2-7).

d. Transmitting triage data to a computer for a centralized recipient from the computers for regional repositories automatically and in at least near real time with its receipt from the computers for the health care facilities (page 5, paragraph 0048, lines 2-7).

e. Analyzing the triage data and determining, based on the analysis, whether a possible bio-emergency exists (page 5, paragraph 0047, lines 5-10).

f. Communicating, from the centralized recipient, information regarding the possible bio-emergency to at least one or more of the regional repositories, one or more health care facilities, and other institutions having an interest in responding to a possible bio-emergency (page 5, paragraph 0048, lines 1-7)

32. As per claim 22, the method of claim 21 is as described above. Reference A further teaches:

a. Compiling the triage data for individual patients to generate volumetric triage data (page 5, paragraph 0051, lines 6-8).

b. Comparing the volumetric triage data with a predetermined threshold; and transmitting a warning in response to said comparing step (page 5, paragraph 0051, lines 6-17);

33. As per claim 23, the method of claim 22 is as described above. Reference A further teaches compiling step is performed by the computer for the regional repositories (page 5, paragraph 0045, lines 1-10; the examiner interprets the database to be the same as regional repository), and the comparing step is performed by the computer for the centralized recipient (page 5, paragraph 0048, lines 1-10; the examiner interprets designated authorities to be the same as centralized recipients).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheetal R. Rangrej whose telephone number is 571-270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRR

SRR 8/7/07

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